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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 19

Application Number: 09/627,694
Filing Date: July 28, 2000
Appellant(s): HOUGHTON ET AL.

Marina T. Larson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 6, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 31 and 33 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Houghton et al. "Recognition of Autoantigens by Patients with Melanoma", vol. 690 (August 12, 1993), pages 59-68

Edited by Frederick M. Ausubel et al. Expression of Proteins in Insect Cells Using Baculoviral Vectors in Current Protocols In Molecular Biology, vol. 2, supplement 10, units 16.8.1-16.8.5, 16.91-16.9.6, 16.10.1-16.10.8 and 16.11.1-16.11.7.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (Annals New York Academy of Sciences 690:59-38, August 12, 1993), in view of Ausubel et al. (Referenced on IDS, page 2, Paper number 4). Houghton discloses a human gp75 differentiation antigen derived from the human melanoma cell line, SK-MEL-19 expressed in the non-human cell line, mouse L

cells(see page 65, "The gp75 Antigen..." section). Houghton does not teach a non-human cell line, wherein the cell line is an insect cell line.

However, Ausubel teaches the preparation of insect cell cultures and expression of proteins, such as a human tyrosinase differentiation antigen in insect cells using baculoviral expression systems. It would have been *prima facie* obvious to one of ordinary skill in the art at would have been motivated to do so with a reasonable expectation of success by teachings in both, Houghton and Ausubel. The Houghton reference provides the basis that gp75 can be cloned. Ausubel affirms the great likelihood of obtaining biologically active products from such methods and host cells due to the baculovirus' efficient promoter strategy and the high infection rate of insect host cells. Ausubel also sets forth that the baculoviral expression system transfected within insect cells yields a significant amount of the protein of interest, which is capable of being cloned, screened, isolated and purified. Furthermore, one of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because it is art known that sources of altered antigen can induce effective immune responses, such as tumor rejection.

(11) Response to Argument

The Appellants argue that "the Examiner has not established a *prima facie* case of obviousness, nor has the Examiner given proper credit to evidence of the properties of the claimed invention." Additional arguments are that "...nothing would direct the person skilled in the art to think of insect cell expression systems" and "contrary to the

Examiner's assertion, Ausubel does not teach a great likelihood of obtaining biologically active products, but rather ...that the system may not work for all proteins and experimentation will be necessary to determine if the system will work for a particular protein". These essential disagreements appear on pages 3-5 of the Brief.

With respect to Appellants argument that proper credit has not been given to evidence of properties, Appellants have not provided any unique or unexpected properties and therefore absent unexpected results, the production of a known desirable and cloned polypeptide by using an art-standard mass-production system like the instant baculovirus system remains *prima facie* obvious.

The prior art provides motivation to establish the case of *prima facie* obviousness. The Houghton reference sets forth that studies of immunogenic tumor antigens such as gp75 provide the basis for experiments within the field of tumor immunology. Immunogenic tumor antigens such as gp75 are defined as "unique" antigens expressed by tumor cells but not by normal cells or independently derived tumors, see abstract on page 59. In effect researchers have capitalized on unique immunogenic tumor antigens and noted their use in tumor immunotherapy.

Furthermore, the Houghton reference does teach that gp75 is a homologue of the mouse brown locus protein as stated by Appellants on page 4, first paragraph. This fact is predicated upon gp75's ability of being cloned. Notwithstanding, the reference also declares that the "gp75 is a tissue-specific antigen expressed in melanocytes", see page 64, last sentence of first paragraph. Accordingly one of ordinary skill in the art would be motivated to mass produce a protein deemed useful as a tool for

experimentation with a reasonable expectation of success. Ausubel states "[b]aculoviruses have emerged as a popular system for overproducing recombinant proteins in eukaryotic cells", see page 16.8.1, column 1, first sentence. "[T]he baculoviral expression system uses a helper-independent virus that can be propagated to high titers in insect cells...making it possible to obtain large amounts of recombinant protein with relative ease", see page 16.8.1, column 1, first paragraph. There is a reasonable expectation of success of producing increased amounts of an antigen interest in a highly regarded expression system such as the baculoviral system and utilizing the produced protein for experimentation.

Appelants present Bouchard et al. (Exhibit A) a reference, which "...describes expression of human tyrosinase cDNA in mouse fibroblasts". Appellants further assert the said reference "...teaches...whether melanosomal proteins in general are expressable at all in mammalian cells which lack melanosomes". Notwithstanding, Bouchard does concern a different protein its teachings do not preclude one of ordinary skill in the art from or dissuade one from implementing the teachings of Houghton and Ausubel in order to mass-produce a protein, such as gp75. Houghton presented the impetus for one of ordinary skill in the art to increase the yield of the gp75 tumor antigen. Houghton acknowledged that "[a] fundamental tenet of tumor immunology is that immune responses against cancer are capable of rejecting tumors. Experimental systems have demonstrated that immunotherapy of cancer is more likely to be effective against immunogenic tumors...[suggesting] that rational strategies for immunotherapy can be built on immunization schemes with well-characterized tumor antigens", see first

paragraph of page 59. One of ordinary skill in the art would recognize that an antigen of interest, particularly gp75 could be used as a diagnostic tool due to its tissue specificity. That fact in itself is motivation for producing increased amounts of gp75 in an effective expression, such as the baculoviral expression system. Ausubel contemplates preparation of large scale production of recombinant proteins. This art recognized eukaryotic expression system's popularity can be attributed to its potentially high protein expression levels. Taking advantage of the system's large-scale insect cell multiplicity inevitably there is high production of recombinant proteins. Absent any evidence contrary to the facts that the baculovirus expression system lends itself to increased propagation of a protein of interest and the said protein would be produced, modified and processed one of ordinary skill in the art would be motivated to combine the teachings of Houghton and Ausubel. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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May 15, 2003

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